



PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Susan Ann Charman, et al.

Examiner: A. Holleran

Serial No.: 09/555,108

Art Unit: 1642

Filed: May 24, 2000

Docket: 13627

Int'l Appln. No. PCT/AU98/00981

Int'l Filing Date: November 26, 1998
For: COMPOSITIONS OF LEUKEMIA
INHIBITORY FACTOR

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Assistant Commissioner for Patents
Washington, DC 20231

DECLARATION UNDER 37 C.F.R. 31.131

Sir:

I, Susan Ann Charman, hereby declare that:

1. I am an applicant of U.S. Patent Application Serial No. 09/555,108 filed May 24, 2000 ("the Application").

2. U.S. Patent No. 6,156,729 entitled "Leukemia Inhibitory Factor For Use In Modulating Inflammation and Pain" by Patterson, et al. (hereinafter "Patterson, et al.") has been identified by the Examiner in an Office Action dated May 9, 2001 as a basis for rejecting pending Claims 1-40 and 43 in the Application. The Patterson, et al. reference was filed on October 15, 1998 and is purportedly based on Provisional Application No. 60/062,049 filed October 15, 1997, now abandoned.

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3. The invention disclosed and claimed in the above-identified application was completed in a WTO member country by me and under my direct supervision and control prior to the filing of the Patterson, et al. reference, i.e. October 15, 1997.

4. As evidence of the completion of the above invention, annexed hereto is Exhibit A. Exhibit A consists of copies of laboratory notebook pages reflecting work performed by me or under my supervision at ^{Victorian College of Pharmacy} 381 Royal Parade ^{Parkville, Vic 3052} demonstrating the completion of the claimed invention prior to the publication of Patterson, et al. Data not pertinent to this invention, including dates have been redacted in preparation of this exhibit.

5. A reduction to practice of the invention disclosed and claimed in the Application and evidenced by Exhibit A, consisted of making a stable LIF formulation at a pH between 3.5 and 6.5 (See, page 104)

6. Specifically, at 8°C and at 25°C, stable formulations of LIF (at 0.4 mg/ml) contain citrate buffer, sorbitol and Tween 80 at pH 5.0. Similar results are obtained when the LIF formulations contain citrate buffer and NaCl at pH 5.0. The LIF formulations maintained stability over eight weeks when stored at 8°C. SAC

7. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under §1001 of Title 18 of the United States code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Susan A. Charman
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